UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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BRITTANY ANN HOUGH and JASON HOUGH

Docket No.:

Plaintiffs,

-against-

COMPLAINT

C.R. BARD, INC., BARD PERIPHERAL VASCULAR, INC., a foreign corporation, and DOES 1 through 100 inclusive,

Defendants.

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Plaintiffs, BRITTANY ANN HOUGH and JASON HOUGH by and through their undersigned attorneys, hereby sue defendants C.R. BARD, INC.; BARD PERIPHERAL VASCULAR, INC.; and DOES 1 through 100 (collectively, the "Defendants") and allege as follows:

PARTIES

1. Plaintiffs BRITTANY ANN HOUGH and her spouse JASON HOUGH at all times relevant to this action resided in and continue to reside in Hartsville, South Carolina. Plaintiff, BRITTANY ANN HOUGH in May 2005 underwent placement of a Bard Recovery® Filter. The Recovery® Filter subsequently fractured in multiple locations. The fractured portions of the device migrated to Plaintiff's vital organs causing injury and damage. Plaintiff was caused to undergo surgery and extensive medical care as a result of the failure of the Recovery® Filter manufactured by Defendants. Fractured shards of the Recovery® Filter remain in Plaintiff's body. Plaintiff has incurred significant medical expenses and has endured extreme pain and suffering, loss of enjoyment of life, disability, and other losses. Plaintiff will require ongoing medical care to monitor the fractured shards in Plaintiff's body to ensure that they do not cause further future injury.

2. Defendant C.R. Bard, Inc. ("Bard") is a corporation duly organized and existing under the laws of the state of Delaware and has its principal place in New Jersey. Bard at all times relevant to this action, designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the Recovery® Filter System to be implanted in patients throughout the United States.

3. Defendant Bard Peripheral Vascular, Inc. ("BPV") is a wholly owned subsidiary corporation of defendant Bard, with its principal place of business at 1625 West 3rd Street, Tempe, Arizona. BPV at all times relevant to this action, designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the Recovery® Filter System to be implanted in patients throughout the United States

4. All references to "Defendants" hereafter shall refer to defendants Bard, BPV, and DOES 1 through 100.

5. The true names, identities, or capacities, whether individual, associate, corporate or otherwise of defendants, DOES 1 through 100, inclusive, are unknown to Plaintiff who, therefore, sues said defendants by such fictitious names. When the true names, identities or capacities of said fictitiously designated defendants are ascertained, plaintiff will seek leave of Court to amend this complaint to insert the true names, identities, and/or capacities of DOE Defendants, together with the proper charging allegations against said DOE Defendants.

6. Plaintiff is informed and believes, and thereon alleges that each of the defendants sued herein as a DOE defendant is responsible in some manner for the acts, omissions, and conduct, which proximately resulted in and/or was a substantial contributing factor in Plaintiff's injuries.

JURISDICTION AND VENUE

7. Jurisdiction is proper in this Court under 28 U.S.C. § 1332(a)(1) because the plaintiff and the defendants are citizens of different states and the amount in controversy exceeds $75,000, exclusive of interest and costs.

8. Venue is proper in this Court under 28 U.S.C. § 1391, as a substantial part of the events or omissions giving rise took place within this judicial district. Specifically, defendant Bard's principal place of business is in New Jersey.

GENERAL FACTUAL ALLEGATIONS

9. Plaintiffs bring this case for serious personal injuries Plaintiff BRITTANY ANN HOUGH suffered as result of a surgically implanted medical device, known as a Recovery® Filter System, fracturing and migrating within her body and causing serious and ongoing physical, emotional, and economic damages.

10. The Recovery® Filter was designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed, and sold by Defendants from approximately November 2002 for the prevention of blood clots (thrombi) from travelling from the lower portions of the body to the heart and lungs.

11. Prior to Plaintiff being implanted with a Recovery® Filter in May, 2005, Defendants knew and should have known that the device was defective and unreasonably dangerous for, *inter alia*, the following reasons:

a. Defendants failed to conduct any clinical testing, such as animal studies, to determine how the device would function once permanently implanted in the human body.

b. Defendants knew and/or should have known that the Recovery® Filter had high rate fracture, migration, and excessive tilting and perforation of the vena cava wall once implanted in the human body. Defendants knew and/or should have known that such failures exposed patients to serious injuries, including: death; hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; severe and persistent pain; perforations of tissue, vessels and organs; and inability to remove the device. Upon information and belief, Defendants also knew or should have known that certain condition or post-implant procedures, such as morbid obesity or open abdominal procedures, could affect the safety and integrity of the device. Further, Defendants knew of should have known that these risks for Recovery® Filter were and are substantially higher than other similar devices.

c. Further, Defendants knew and/or should have known that the Recovery® Filter contained conditions, which Defendants did not intend, which resulted in the device not performing as safely and the ordinary consumer would expect.

d. Despite being aware of these risks, Defendants misrepresented, omitted, and/or failed to provide adequate warnings of these risks or instructions for safe use.

e. Even when Defendants designed and began marketing what they alleged to be a device that specifically reduced these risks, they still failed to issue a recall or notify consumers that a safer device was available.

A. INFERIOR VENA CAVA FILTERS GENERALLY

12. Inferior vena cava ("IVC") filters first came on to the medical market in the 1960's. Over the years, medical device manufacturers have introduced several different designs of IVC filters.

13. An IVC filter is a device that is designed to filter or "catch" blood clots (called "thrombi") that travel from the lower portions of the body to the heart and lungs. IVC filters may be designed to be implanted, either permanently or temporarily, in the human body, more specifically, within the inferior vena cava.

14. The inferior vena cava is a vein that returns blood to the heart from the lower portions of the body. In certain people, for various reasons, thrombi travel from the vessels in the legs and pelvis, through the vena cava and into the lungs. Often times, these thrombi develop in the deep leg veins. These thrombi are called "deep vein thrombosis" or "DVT". Once thrombi reach the lungs, they are considered "pulmonary emboli" or "PE". Pulmonary emboli present risks to human health. They can, and often do, result in death.

15. Certain people are at increased risk for the development of DVT or PE. For instance, someone who undergoes knee or hip joint replacement surgery is at risk for developing DVT/PE. Obese patients are also at increased risk for DVT/PE. So too are people who have vascular diseases or whom have experienced previous strokes. A number of other conditions predispose people to develop DVT/PE, including "coagulopathies" and clotting disorders.

16. Those people at risk for DVT/PE can undergo medical treatment to manage the risk. For example, a doctor may prescribe medications like Heparin, Warfarin, or Lovenox to regulate the clotting factor of the blood. In some people who are at high risk for DVT/PE, or who cannot manage their conditions with medications, physicians may recommend surgically implanting an IVC filter to prevent thromboembolitic events.

17. As stated above, IVC filters have been on the market for decades. The first IVC filters marketed were permanent filters. These devices were designed to be left in a patient's IVC permanently and have long-term follow-up data (of up to 20 years and longer) supporting their use and efficacy. Beginning in 2003, manufacturers also began marketing what are known as optional or retrievable filters. These filters are designed so that they can be surgically removed from a patient after the risk of PE has subsided. These IVC filter designs, however, were not intended to remain within the human body for indeterminate periods of time. In other words, the initial designs of retrievable IVC filters were intended to remain implanted for a finite period of time. The Recovery® Filter System and the subsequent G2® Filter manufactured by Bard and BPV are examples of retrievable filters.

B. THE RECOVERY FILTER®

i. FDA Clearance and Intended Use

18. In 2002, Bard and BPV submitted a notification of intent to the FDA to market the "Recovery® Filter System" (hereafter "Recovery®" or "Recovery® Filter") for the prevention of recurrent pulmonary embolism by placement in the inferior vena cava.[1] On November 27, 2002, the FDA cleared the Recovery® Filter for marketing and use in the prevention of recurrent pulmonary embolism via *permanent* placement in the vena cava in the

[1] Bard and BPV submitted the notification under Section 510(k) of the United States Food, Drug and Cosmetic Act ("Act") of 1976 (21 U.S.C. 321 *et seq*). The 510(k) review process requires any entity engaged in the design, manufacture, distribution or marketing of a device intended for human use to notify the FDA 90 days before it intends to market the device and to establish that the device is substantially equivalent to a legally marketed predicate device. (21 C.F.R. §§ 807.81, 807.92(a)(3)). Substantial equivalence means that the new device has the same intended use and technological characteristics as the predicate device. This approval process allows a manufacturer to bypass the rigorous safety scrutiny required by the pre-market approval process.

following situations: (a) pulmonary thromboembolism when anticoagulants are contraindicated; (b) failure of anticoagulant therapy for thromboembolic disease; (c) emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced; and (d) chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

19. In April 2003, Bard and BPV submitted a Section 510(k) premarket notification of intent to market the Recovery® Filter for the additional intended use of *optional retrieval*. The FDA cleared this additional intended use on July 25, 2003.

20. Bard and BPV began actually marketing the device in April 2003, but did not begin full market release until 2004. Bard and BPV were aware that the Recovery® filter was also used extensively off-label, including for purely prophylactic reasons for trauma patients or patients with upcoming surgeries such as bariatric procedures.

ii. What Is It and How Is It Used

21. The Recovery® Filter consists of two (2) levels of six (6) radially distributed NITINOL struts that are designed to anchor the filter into the inferior vena cava and to catch any embolizing clots. There are six short struts, which are commonly referred to as the arms, and six long struts, which are commonly referred to as the legs. Each strut is held together by a single connection to a cap located at the top of the device. According to the Patent filed for this device, the short struts are primarily for "centering" or "positioning" with the vena cava, and the long struts with attached hooks are designed to primarily to prevent the device from migrating in response to "normal respiratory movement" or "pulmonary embolism."

22. As noted above, the Recovery® Filter is constructed with NITINOL, which is an acronym that stands for Nickel Titanium Naval Ordnance Laboratory. NITINOL possesses "shape memory." That is, NITINOL will change shape according to changes in temperature, and then, retake its prior shape after returning to its initial temperature. When placed in saline, therefore, the NITINOL struts become soft and can be straightened to allow delivery through a small diameter catheter. The metal struts then reassume their original shape when warmed to body temperature in the vena cava.

23. The Recovery® filter is inserted by a catheter that is guided by a physician through a blood vessel into the inferior vena cava. The Recovery® Filter is designed to be retrieved in a similar fashion. The implanting physician normally reviews an imaging study prior to placement to determine size of IVC, renal vein location, and to identify any venous anomalies or clots in the vena cava. Following placement, the physician will normally use an imaging study to confirm successful placement.

iii. Inherent Risks of the Recovery® Filter

24. The Recovery® Filter is prone to an unreasonably high risk of failure and patient injury following placement in the human body. Multiple studies have reported Bard's Recovery® Filter to have a fracture and migration rate ranging from 21% to 31.7%.[2] When such failures occur, shards of the device or the entire device can travel to the heart, where it can cause cardiac tamponade, perforation of the atrial wall, myocardial infarction and death. These fractured shards may also become too embedded in tissue or migrate to locations, such as the lungs, such that they are too dangerous to remove. These patients are exposed to a lifetime of future risk.

25. The Recovery® Filter similarly poses a high risk of tilting and perforating the vena cava walls. When such failures occur, the device can perforate the duodenum, small bowel, ureter, which may lead to retroperitoneal hematomas, small-bowel obstructions, extended periods of severe pain, and/or death. Further, given the risks of injury in attempting to remove devices that have perforated the vena cava, the device may be irremovable. These patients are faced with a lifetime of future risk.

26. The Recovery Filter failures described above occur at a substantially higher rate than with other IVC filters.

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[2] *See e.g.,* Hull JE, Robertson SW. Bard Recovery Filter: evaluation and management of vena cava limb perforation, fracture, and migration. *J Vasc Interv Radiol.* 2009;20(1):52-60; Nicholson W, *et al.* Prevalence of Fracture and Fragment Embolization of the Bard Recovery and Bard G2 Cava Filters and Clinical Implications Including Cardiac Perforation and Tamponade. *Arch. Int. Med.* 2010 Nov.; 170:1827-31.

27. The adverse event reports (AERs) associated with IVC filter devices demonstrates that Bard's IVC Filters are far more prone to device failure then are other similar devices. A review of the FDA MAUDE database from the years 2004-2008 reveals data to establish that Bard's IVC filters are responsible for the following percentages of all AERs:

a. 50% of all adverse events
b. 64% of all occurrences of migration of the device
c. 69% of all occurrences of vena cava wall perforation
d. 70% of all occurrences of filter fracture.

28. These failures are attributable, in part, to the fact that the Recovery® Filter was designed so as to be unable to withstand the normal anatomical and physiological loading cycles exerted *in vivo*.

29. In addition to design defects, the Recovery® Filter suffers from manufacturing defects. These manufacturing defects include, but are not limited to, the existence of "draw markings" and circumferential grinding markings on the exterior of the surface of the device. The presence of these draw markings and/or circumferential grinding markings further compromises the structural integrity of the device while *in vivo*. In particular, the Recovery Filter is prone to fail at or near the location of draw markings/circumferential grinding markings on the struts of the device. Put simply, the Recovery Filter is not of sufficient strength to withstand normal placement within the human body. The presence of the aforementioned exterior manufacturing defects makes the device more susceptible to failure.

iv. What Bard and BPV Knew or Should Have Known

30. Bard and BPV knew that no clinical testing, such as animal studies, was conducted to determine whether the Recovery® Filter would perform safely once implanted in the human body and subjected normal *in vivo* stresses.

31. Soon after the Recovery® Filter's introduction to the market in 2003, Bard and BPV began receiving large numbers of adverse event reports ("AERs") from health care providers reporting that the Recovery® Filter was fracturing post-implantation and that fractured pieces and/or the entire device were migrating throughout the human body, including to the heart and lungs. Bard and BPV also received large numbers of AERs reporting that the Recovery®

Filter was found to have excessively tilted and/or perforated the inferior vena cava post-implantation. These failures were often associated with reports of severe patient injuries such as:

a. death;

b. hemorrhage;

c. cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart);

d. cardiac arrhythmia and other symptoms similar to myocardial infarction;

e. severe and persistent pain;

f. and perforations of tissue, vessels and organs.

32. Within the first year of full market release of the Recovery® Filter, Bard and BPV received at least 32 AERs reporting that the Recovery® Filter had fractured *in vivo* and at least 22 AERs reporting that the entire device had migrated *in vivo*. Of the 22 reported migration failures, at least nine (9) were reported to have been associated with patient death.

33. From 2003 through September 2005, Bard and BPV received ever growing numbers of AERs reporting the above described failures and patient injuries. Defendants knew or should have known that the failure rates associated with the Recovery® Filter were substantially higher than other similar products on the market.

v. Market Withdrawal, but no Recall

34. In late 2004 or early 2005, Bard and BPV, without notifying consumers of the design and manufacturing flaws inherent in the Recovery® Filter, began redesigning the Recovery® Filter in an attempt to correct those flaws. The redesigned filter is known as the G2® Filter, which stands for second generation Recovery® Filter. Once Bard and BPV had obtained FDA approval to market the redesigned product in or around August 2005, Bard and BPV quietly stopped marketing the Recovery® Filter. Bard and BPV failed, however, to make any effort to notify consumers of the risk inherent in the use of the Recovery® Filter.

C. THE G2® FILTER SYSTEM

35. On August 10, 2005, Bard and BPV submitted a Section 510(k) premarket notification of intent to market the G2® Filter for the prevention of recurrent pulmonary

embolism via placement in the inferior vena cava. Bard and BPV cited the Recovery® Filter as the substantially equivalent predicate device. Bard and BPV stated that the differences between the Recovery® Filter and the G2® Filter were primarily dimensional and no material changes or additional components were added. On August 29, 2005, the FDA cleared the G2® Filter for the same intended uses as the Recovery® Filter, except that it was not cleared for retrievable use.[3]

36. Bard and BPV marketed the G2® Filter as having "enhanced fracture resistance," "improved centering," and "increased migration resistance." However, Bard and BPV again failed to conduct adequate clinical testing, such as animal studies, to ensure that the device would perform safely and effectively once implanted in the human body and subjected *in vivo* stresses. Not surprisingly, the G2® Filter's design causes it to be of insufficient integrity and strength to withstand normal *in vivo* body stresses within the human body so as to resist fracturing, migrating, tilting, and/or perforating the inferior vena cava.

37. Also, like its predecessor, in addition to design defects, the G2® Filter suffers from manufacturing defects. These manufacturing defects include, but are not limited to, the existence of "draw markings" and circumferential grinding markings on the exterior of the surface of the device. The presence of these draw markings and/or circumferential grinding markings further compromises the structural integrity of the G2® Filter while *in vivo*. In particular, the G2® Filter is prone to fail at or near the location of draw markings/circumferential grinding markings on the struts of the device. Put simply, the G2® Filter is not of sufficient strength to withstand normal placement within the human body. The presence of the aforementioned exterior manufacturing defects makes the device more susceptible to fatigue failure.

38. Thus, the G2® Filter shares the same defects and health risks as its predicate device.

39. As with the Recovery® Filter, Bard and BPV immediately began receiving large numbers of AERs reporting that the G2® Filter was, *inter alia*, fracturing, migrating, excessively

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[3] The FDA did not clear the G2® Filter to be used as a retrievable filter until January 15, 2008.

tilting, and perforating the vena cava once implanted. These failures were again often associated with reports of severe patient injuries such as:

a. death;

b. hemorrhage;

c. cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart);

d. cardiac arrhythmia and other symptoms similar to myocardial infarction;

e. severe and persistent pain;

f. and perforations of tissue, vessels and organs.

40. Defendants represent the fracture rate of the G2® Filter to be 1.2%. Based upon a review of the data available in the public domain (including the FDA MAUDE database statistics and the published medical literature), this representation does not accurately reflect the true incidence of device fracture for the G2® Filter.

41. A review of the MAUDE database from the years 2004-2008 reveals data to establish that the Bard and BPV's vena cava filters (including the G2® Filter) are responsible for the majority of all reported adverse events related to inferior vena cava filters.

D. BARD AND BPV'S KNOWLEDGE OF THE RISK OF FAILURE AND RESULTING DANGERS

42. Upon information and belief, Plaintiff alleges that as early as 2003, Bard and BPV were aware and had knowledge of the fact that the Recovery® Filter was defective and unreasonably dangerous and was causing injury and death to patients who had received it. Similarly, Bard and BPV were aware as early as 2005 that the G2® Filter System was defective and unreasonably dangerous and was causing injury and death to patients who had received it.

43. Data establishes that the failure rates of the Recovery® Filter and G2® Filter are/were exceedingly higher than the rate that Bard and BPV have in the past, and currently continue to publish to the medical community, members of the public. Further, Bard and BPV were aware or should have been aware that the Recovery® Filter and G2® Filter have substantially higher failure rates than do other similar products on the market, yet Defendants have failed to warn consumers of this fact.

44. Upon information and belief, from the time the G2® Filter System became available on the market, the Defendants Bard and BPV embarked on an aggressive campaign of "off label marketing" concerning the G2® Filter System. This included representations made to physicians, healthcare professionals, and other members of the medical community that the G2® Filter System was safe and effective for retrievable use prior to the FDA approving the G2® Filter System for retrievable use.

45. The conduct of Bard and BPV as alleged in this Complaint constitutes willful, wanton, gross, and outrageous corporate conduct that demonstrates a conscious disregard for the safety of Plaintiff. Bard and BPV had actual knowledge of the dangers presented by the Recovery Filter® and G2® Filter, yet consciously failed to act reasonably to:

a. Inform or warn Plaintiff, Plaintiff's physicians, or the public at large of these dangers;

b. Establish and maintain an adequate quality and post-market surveillance system; and

c. Recall the Recovery® Filter and G2® Filter from the market.

46. Despite having knowledge as early as 2003 of the unreasonably dangerous and defective nature of the Recovery® Filter, Bard and BPV consciously disregarded the known risks and continued to actively market and offer for sale the Recovery® and G2® Filter Systems.

47. Plaintiff further alleges that the Defendants acted in willful, wanton, gross and total disregard for the health and safety of the users or consumers of their Recovery® Filter and G2® Filter Systems, acted to serve their own interests, and having reason to know and consciously disregarding the substantial risk that their product might kill or significantly harm patients, or significantly injure the rights of others, consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons.

SPECIFIC FACTUAL ALLEGATIONS AS TO PLAINTIFF

48. In May, 2005, Plaintiff underwent surgical placement of a Recovery® Filter

49. This Recovery® Filter device was designed, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold by Defendants Bard and BPV.

50. The Recovery® Filter subsequently fractured in multiple locations. The fractured portions of the device migrated to Plaintiff's vital organs causing injury and damage. Plaintiff was caused to undergo surgery and extensive medical care as a result of the failure of the Recovery® Filter manufactured and distributed by Defendants. Plaintiff underwent partially successful complex surgery on November 25, 2014 to remove the fractured device. At removal, an imbedded free fragment was noted. Due to the risk of complications from any removal attempt, the free fragment was left in place. Plaintiff has suffered and will continue to suffer significant medical expenses, pain and suffering, loss of enjoyment of life, disability, and other losses. Plaintiff will require ongoing medical care to monitor the fragment in Plaintiff's body to ensure that they do not cause future injury.

FRUADULENT CONCEALMENT

51. Any applicable statutes of limitations have been tolled by the knowing and active concealment and denial of material facts known by Defendants when they had a duty to disclose those facts. They have kept Plaintiff ignorant of vital information essential to the pursuit of their claims, without any fault or lack of diligence on Plaintiff's part, for the purpose of obtaining delay on Plaintiff's part in filing on their causes of action. Defendants' fraudulent concealment did result in such delay.

52. Defendants are estopped from relying on the statute of limitations defense because Defendants failed to timely disclose, among other things, facts evidencing the defective and unreasonably dangerous nature of the Recovery® and G2® Filter Systems.

53. The Defendants are and were under a continuing duty to disclose the true character, quality and nature of the device that was implanted in Plaintiff, but instead they concealed them. Defendants' conduct, as described in this complaint, amounts to conduct purposely committed, which Defendants must have realized was dangerous, heedless and reckless, without regard to the consequences or the rights and safety of Plaintiff.

CORPORATE/VICARIOUS LIABILITY

54. At all times herein mentioned, each of the Defendants was the agent, servant, partner, aider and abettor, co-conspirator and/or joint venturer of each of the other Defendants

herein and was at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and/or joint venture and rendered substantial assistance and encouragement to the other Defendants, knowing that their collective conduct constituted a breach of duty owed to the Plaintiff.

55. There exists and, at all times herein mentioned, there existed a unity of interest in ownership between certain Defendants and other certain Defendants such that any individuality and separateness between the certain Defendants has ceased and these Defendants are the alter ego of the other certain Defendants and exerted control over those Defendants. Adherence to the fiction of the separate existence of these certain Defendants as entities distinct from other certain Defendants will permit an abuse of the corporate privilege and would sanction a fraud and/or would promote injustice.

56. At all times herein mentioned, Defendants, and each of them, were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing and/or advertising for sale, and selling products for use by the Plaintiff. As such, each Defendant is individually, as well as jointly and severally, liable to the Plaintiff for Plaintiff's damages.

57. At all times herein mentioned, the officers and/or directors of the Defendants named herein participated in, authorized and/or directed the production and promotion of the aforementioned products when they knew, or with the exercise of reasonable care and diligence should have known, of the hazards and dangerous propensities of said products, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by the Plaintiff.

FIRST CAUSE OF ACTION
NEGLIGENCE

58. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

59. At all times relevant to this cause of action, the Defendants Bard, BPV, and DOES 1 -100 were in the business of designing, developing, setting specifications, manufacturing, marketing, selling, and distributing the Recovery® and G2® Filters.

60. Defendants designed, manufactured, marketed, inspected, labeled, promoted, distributed and sold the Recovery® Filter that was implanted in Plaintiff.

61. Defendants had a duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the Recovery® Filter so as to avoid exposing others to foreseeable and unreasonable risks of harm.

62. Defendants knew or reasonably should have known that the Recovery® Filter was dangerous or was likely to be dangerous when used in its intended or reasonably foreseeable manner.

63. At the time of manufacture and sale of the Recovery® Filter (2002 until October 2005), Defendants knew or should have known that the Recovery® Filter:

a. Was designed and manufactured in such a manner so as to present an unreasonable risk of fracture of portions of the device;

b. Was designed and manufactured so as to present a unreasonable risk of migration of the device and/or portions of the device; and/or

c. Was designed and manufactured so as to present a unreasonable risk of the device tilting and/or perforating the vena cava wall;

d. Was designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body.

64. At the time of manufacture and sale of the Recovery® Filter (2002 until October 2005), Defendants knew or should have known that using the Recovery® Filter in its intended use or in a reasonably foreseeable manner created a significant risk of a patient suffering severe health side effects, including, but not limited to: hemorrhage; cardiac/pericardial tamponade;

cardiac arrhythmia and other symptoms similar to myocardial infarction; perforations of tissue, vessels and organs; and other severe personal injuries and diseases, which are permanent in nature, including, but not limited to, death, physical pain and mental anguish, scarring and disfigurement, diminished enjoyment of life, continued medical care and treatment due to chronic injuries/illness proximately caused by the device; and the continued risk of requiring additional medical and surgical procedures including general anesthesia, with attendant risk of life threatening complications.

65. Defendants knew or reasonably should have known that consumers of the Recovery® Filter would not realize the danger associated with using the device in its intended use and/or in a reasonably foreseeable manner.

66. Defendants breached their to duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the Recovery® Filter in, among other ways, the following acts and omissions:

a. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking safety measures to reduce or avoid harm;

b. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other device available for the same purpose;

c. Failing to use reasonable care in manufacturing the product and producing a product that differed from their design or specifications or from other typical units from the same production line;

d. Failing to use reasonable care to warn or instruct, including pre and post sale, Plaintiff, Plaintiff's physicians, or the general health care community about the Recovery® Filter's substantially dangerous condition or about facts making the product likely to be dangerous;

e. Failing to perform reasonable pre and post-market testing of the Recovery® Filter to determine whether or not the product was safe for its intended use;

f. Failing to provide adequate instructions, guidelines, and safety precautions, including pre and post sale, to those persons to whom it was reasonably foreseeable would prescribe, use, and implant the Recovery® Filter;

g. Advertising, marketing and recommending the use of the Recovery® Filter, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with and inherent in the use of the Recovery® Filter;

h. Representing that the Recovery® Filter was safe for its intended use when in fact, Defendants knew and should have known the product was not safe for its intended purpose;

i. Continuing manufacture and sale of the Recovery® Filter with the knowledge that said product was dangerous and not reasonably safe, and failing to comply with FDA good manufacturing regulations;

j. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the Recovery® Filter so as to avoid the risk of serious harm associated with the use of the Recovery® Filter;

k. Advertising, marketing, promoting and selling Recovery® Filter for uses other than as approved and indicated in the product's label;

l. Failing to establish an adequate quality assurance program used in the manufacturing of the Recovery® Filter;

m. Failing to establish and maintain and adequate post-market surveillance program.

67. A reasonable manufacturer, distributor, or seller under the same or similar circumstances would not have engaged in the before-mentioned acts and omissions.

68. As a direct and proximate result of the foregoing negligent acts and omissions by Defendants, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

SECOND CAUSE OF ACTION
STRICT PRODUCTS LIABILITY - FAILURE TO WARN

69. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

70. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Recovery® Filter, including the one implanted into Plaintiff, into the stream of commerce and in the course of same, directly advertised and marketed the device to consumers or persons responsible for consumers.

71. At the time Defendants designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the device into the stream of commerce, Defendants knew or should have known the device presented an unreasonable danger to users of the product when put to its intended and reasonably anticipated use. Specifically, Defendants knew or should have known at the time they manufactured, labeled, distributed and sold the Recovery® Filter, which was implanted in Plaintiff, that the Recovery® Filter, *inter alia*, posed a significant and higher risk than other similar devices of device failure (fracture, migration, tilting, and perforation of the vena cava wall) and resulting serious injuries. Upon information and belief, Defendants also knew or should have known that certain conditions or post-implant procedures, such as morbid obesity or open abdominal procedures, could affect the safety and integrity of the device.

72. Therefore, Defendants had a duty to warn of the risk of harm associated with the use of the device and to provide adequate instructions on the safe and proper use of the device. Defendants further had a duty to warn of dangers and proper safety instructions that it became aware of even after the device was distributed and implanted in Plaintiff.

73. Despite this duty, Defendants failed to adequately warn of material facts regarding the safety and efficacy of the Recovery® Filter, and further failed to adequately provide instructions on the safe and proper use of the device.

74. No health care provider, including Plaintiff's, or patient would have used the device in the manner directed, had those facts been made known to the prescribing healthcare providers and/or ultimate users of the device.

75. The health risks associated with the device as described herein are of such a nature that ordinary consumers would not have readily recognized the potential harm.

76. Plaintiff and Plaintiff's health care providers used the device in a normal, customary, intended, and foreseeable manner, namely as a surgically implanted device used to prevent pulmonary embolisms.

77. Therefore, the Recovery® Filter implanted in Plaintiff was defective and unreasonably dangerous at the time of release into the stream of commerce due to inadequate warnings, labeling and/or instructions accompanying the product.

78. The Recovery® Filter implanted in Plaintiff was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed and sold by Defendants.

79. As a direct and proximate result of Defendants' lack of sufficient warning and/or instructions, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

THIRD CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – DESIGN DEFECTS

80. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

81. At all times relevant to this action, Defendants developed, tested, designed, manufactured, inspected, labeled, promoted, distributed and sold into the stream of commerce the Recovery® Filter, including the one implanted in Plaintiff.

82. The Recovery® Filter was expected to, and did, reach its intended consumers without substantial change in the condition in which it was in when it left Defendants' possession. In the alternative, any changes that were made to Recovery® Filter implanted in Plaintiff were reasonably foreseeable to Defendants.

83. The Recovery® Filter implanted in Plaintiff was defective in design because it failed to perform as safely as persons who ordinarily use the product would have expected at the time of use.

84. The Recovery® Filter implanted in Plaintiff was defective in design, in that its risks of harm exceeded its claimed benefits.

85. Plaintiff and Plaintiff's health care providers used the Recovery® Filter in a manner that was reasonably foreseeable to Defendants.

86. Neither Plaintiff, nor Plaintiff's health care providers could have by the exercise of reasonable care discovered the devices defective condition or perceived its unreasonable dangers prior to Plaintiff's implantation with the device.

87. As a direct and proximate result of the Recovery® Filter's defective design, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

FOURTH CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

88. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

89. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Recovery® Filter that was implanted into Plaintiff.

90. The Recovery® Filter implanted in Plaintiff contained a condition, which Defendants did not intend, at the time it left Defendants' control and possession.

91. Plaintiff and Plaintiff's health care providers used the device in a manner that was reasonably foreseeable to Defendants.

92. As a result of this condition, the product injured Plaintiff and failed to perform as safely as the ordinary consumer would expect when used in a reasonably foreseeable manner.

93. As a direct and proximate result of the Recovery® Filter's manufacturing defect, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

FIFTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

94. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

95. At all times relevant to this action, Defendants designed, researched, developed, manufactured, tested, labeled, inspected, advertised, promoted, marketed, sold, and distributed into the stream of commerce the Recovery® Filter for use as a surgically implanted device used to prevent pulmonary embolisms and for uses other than as approved and indicated in the product's instructions, warnings, and labels.

96. At the time and place of the sale, distribution, and supply of the Defendants' Recovery® Filter System to Plaintiff by way of Plaintiff's health care providers and medical facilities, Defendants expressly represented and warranted, by labeling materials submitted with the product, that the Recovery® Filter System was safe and effective for its intended and reasonably foreseeable use.

97. Defendants knew of the intended and reasonably foreseeable use of the Recovery® Filter, at the time they marketed, sold, and distributed the product for use by Plaintiff, and impliedly warranted the product to be of merchantable quality, and safe and fit for its intended use.

98. Defendants impliedly represented and warranted to the healthcare community, Plaintiff and Plaintiff's health care providers, that the Recovery® Filter was safe and of merchantable quality and fit for the ordinary purpose for which the product was intended and marketed to be used.

99. The representations and implied warranties made by Defendants were false, misleading, and inaccurate because the Recovery® Filter was defective, unsafe, unreasonably dangerous, and not of merchantable quality, when used in its intended and/or reasonably foreseeable manner. Specifically, at the time of Plaintiff's purchase of the Recovery® Filter from the Defendants, through Plaintiff's physicians and medical facilities, it was not in a merchantable condition in that:

a. It was designed in such a manner so as to be prone to a statistically high incidence of failure, including fracture, migration, excessive tilting, and perforation of the inferior vena cava;

b. It was designed in such a manner so as to result in a statistically significant incidence of injury to the organs and anatomy; and

c. It was manufactured in such a manner so that the exterior surface of the Recovery® Filter System was inadequately, improperly and inappropriately prepared and/or finished causing the device to weaken and fail.

100. Plaintiff and Plaintiff's health care providers reasonably relied on the superior skill and judgment of Defendants as the designers, researchers and manufacturers of the product, as to whether Recovery® Filter was of merchantable quality and safe and fit for its intended use, and also relied on the implied warranty of merchantability and fitness for the particular use and purpose for which the Recovery® Filter was manufactured and sold.

101. Defendants placed the Recovery® Filter into the stream of commerce in a defective, unsafe, and unreasonably dangerous condition, and the product was expected to and did reach Plaintiff without substantial change in the condition in which the Recovery® Filter was manufactured and sold.

102. Defendants breached their implied warranty because their Recovery® Filter was not fit for its intended use and purpose.

103. As a proximate result of Defendants breaching their implied warranties, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

SIXTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

104. Plaintiffs re-allege and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

105. At all times relevant to this cause, and as detailed *supra*, Defendants negligently provided Plaintiff, Plaintiff's health care providers, and the general medical community with false or incorrect information, or omitted or failed to disclose material information concerning the Recovery® Filter, including, but not limited to, misrepresentations relating to the following subject areas:

a. The safety of the Recovery® Filter;

b. The efficacy of the Recovery® Filter;

c. The rate of failure of the Recovery® Filter; and

d. The approved uses of the Recovery® Filter.

106. The information distributed by Defendants to the public, the medical community and Plaintiff's health care providers was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the Recovery® Filter. Defendants made the foregoing misrepresentations knowing that they were false or without reasonable basis. These materials included instructions for use and warning document that was included in the package of the Recovery® Filter that was implanted in Plaintiff.

107. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff's health care providers; to gain the confidence of the public and the medical community, including Plaintiff's health care providers; to falsely assure them of the quality of the Recovery® Filter and its fitness for use; and to induce the public and the medical community, including Plaintiff's healthcare providers to request, recommend, prescribe, implant, purchase, and continue to use the Recovery® Filter.

108. The foregoing representations and omissions by Defendants were in fact false. The Recovery® Filter is not safe, fit, and effective for human use in its intended and reasonably foreseeable manner. The use of the Recovery® Filter is hazardous to the user's health, and said device has a serious propensity to cause users to suffer serious injuries, including without limitation, the injuries Plaintiff suffered. Further, the device has a significantly higher rate of failure and injury than do other comparable devices.

109. In reliance upon the false and negligent misrepresentations and omissions made by Defendants, Plaintiff and Plaintiff's health care providers were induced to, and did use the Recovery® Filter, thereby causing Plaintiff to sustain severe and permanent personal injuries.

110. Defendants knew and had reason to know that Plaintiff, Plaintiff's health care providers, and the general medical community did not have the ability to determine the true facts intentionally and/or negligently concealed and misrepresented by Defendants, and would not have prescribed and implanted same, if the true facts regarding the device had not been concealed and misrepresented by Defendants.

111. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects in the form of dangerous injuries and damages to persons who are implanted with the Recovery® Filter.

112. At the time, Defendants failed to disclose and misrepresented the foregoing facts, and at the time Plaintiff used the Recovery® Filter, Plaintiff and Plaintiff's health care providers were unaware of said Defendants' negligent misrepresentations and omissions.

113. Plaintiff, Plaintiff's health care providers and general medical community reasonably relied upon misrepresentations and omissions made by Defendants where the concealed and misrepresented facts were critical to understanding the true dangers inherent in the use of the Recovery® Filter.

114. Plaintiff and Plaintiff's health care provider's reliance on the foregoing misrepresentations and omissions by Defendants' was the direct and proximate cause of Plaintiff's injuries as described herein.

PUNITIVE DAMAGES ALLEGATIONS

115. Plaintiffs re-allege each and every allegation in this Complaint and incorporate each allegation into this Count, as if set forth at length, in its entirety.

116. Plaintiff is entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, malicious acts, omissions, and conduct, and their complete and total reckless disregard for the public safety and welfare.

117. Defendants had knowledge of, and were in possession of evidence demonstrating that, the Recovery® Filter was defective and unreasonably dangerous and had a substantially higher failure rate than did other similar devices on the market. Yet, Defendants failed to:

a. Inform or warn Plaintiff or her health care providers of the dangers;

b. To establish and maintain an adequate quality and post-market surveillance system; and

c. Recall the Recovery® Filter from the market

118. Defendants acted to serve their own interests and having reasons to know and consciously disregarding the substantial risk that their product might kill or significantly harm patients, or significantly injure the rights of others, and consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons.

119. As a direct, proximate, and legal result of Defendants' acts and omissions a described herein, and Plaintiff implantation with Defendants' defective product, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

SEVENTH CAUSE OF ACTION
LOSS OF CONSORTIUM

120. . Plaintiffs re-allege each and every allegation in this Complaint and incorporate each allegation into this Count, as if set forth at length, in its entirety.

121. Plaintiff, JASON HOUGH, is the spouse of plaintiff, BRITTANY ANN HOUGH, and as such is entitled to the services, society, companionship, consortium and support of the plaintiff, BRITTANY ANN HOUGH.

122. That by reason of the foregoing plaintiff, JASON HOUGH, was deprived of the services, society, companionship, consortium and support of plaintiff, and has incurred and will continue to incur his future medical expenses, all to her damage in an amount that exceeds the sum or value of $75,000.00 exclusive of interests and costs

WHEREFORE, Plaintiffs pray for relief on the entire complaint, as follows:

AS TO THE FIRST CAUSE OF ACTION FOR NEGLIGENCE AGAINST DEFENDANTS BARD, BPV AND DOES 1 THROUGH 100

1. General damages according to proof at the time of trial;

2. Medical and other special damages, past, present, and future, according to proof at the time of trial;

3. For pre-judgment and post-judgment interest pursuant to the laws of the State of New York;

4. Costs of suit incurred herein;

5. Punitive damages; and

6. For such other and further relief as the court may deem just and proper.

AS TO THE SECOND CAUSE OF ACTION FOR STRICT LIABILITY – FAILURE TO WARN AGAINST DEFENDANTS BARD, BPV AND DOES 1 THROUGH 100

1. General damages according to proof at the time of trial;

2. Medical and other special damages, past, present, and future, according to proof at the time of trial;

3. For pre-judgment and post-judgment interest

4. Costs of suit incurred herein;

5. Punitive damages; and

6. For such other and further relief as the court may deem just and proper.

AS TO THE THIRD CAUSE OF ACTION FOR STRICT LIABILITY – DESIGN DEFECT AGAINST DEFENDANTS BARD BPV, AND DOES 1 THROUGH 100

1. General damages according to proof at the time of trial;

2. Medical and other special damages, past, present, and future, according to proof at the time of trial;

3. For pre-judgment and post-judgment interest

4. Costs of suit incurred herein;

5. Punitive damages; and

6. For such other and further relief as the court may deem just and proper.

AS TO THE FOURTH CAUSE OF ACTION FOR STRICT LIABILITY – MANUFACTURING DEFECT AGAINST DEFENDANTS BARD, BPV AND DOES 1 THROUGH 100

1. General damages according to proof at the time of trial;

2. Medical and other special damages, past, present, and future, according to proof at the time of trial;

3. For pre-judgment and post-judgment interest

4. Costs of suit incurred herein;

5. Punitive damages; and

6. For such other and further relief as the court may deem just and proper.

AS TO THE FIFTH CAUSE OF ACTION FOR BREACH OF IMPLIED WARRANTY AGAINST DEFENDANTS BARD, BPV AND DOES 1 THROUGH 100

1. General damages according to proof at the time of trial;

2. Medical and other special damages, past, present, and future, according to proof at the time of trial;

3. For pre-judgment and post-judgment interest

4. Costs of suit incurred herein; and

5. For such other and further relief as the court may deem just and proper.

AS TO THE SIXTH CAUSE OF ACTION FOR NEGLIGENT MISREPRESENTATION AGAINST DEFENDANTS BARD, BPV AND DOES 1 THROUGH 100

1. General damages according to proof at the time of trial;

2. Medical and other special damages, past, present, and future, according to proof at the time of trial;

3. For pre-judgment and post-judgment interest

4. Costs of suit incurred herein; and

5. For such other and further relief as the court may deem just and proper.

AS TO THE SEVENTH CAUSE OF ACTION FOR LOSS OF CONSORTIUM AGAINST DEFENDANTS BARD, BPV AND DOES 1 THROUGH 100

1. General damages according to proof at the time of trial;

2. Medical and other special damages, past, present, and future, according to proof at the time of trial;

3. For pre-judgment and post-judgment interest

4. Costs of suit incurred herein; and

5. For such other and further relief as the court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury on all issues.

Dated: Melville, New York
March 13, 2015

Respectfully Submitted,

/s/ David B. Krangle (DBK 8085)
David B. Krangle (DBK 8085)
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